MEDICAL DEVICE MANUFACTURING LICENSE APPLICATION

PLEASE COMPLETE THIS FORM FULLY—INCOMPLETE APPLICATIONS WILL BE RETURNED

See page 2 for instructions.

☐ NEW APPLICANT ☐ RENEWAL APPLICANT ☐ RELOCATION ☐ OWNERSHIP CHANGE ☐ OWNERSHIP AND LOCATION CHANGE

1. Name of Firm			9. Facility Operator (name and title)		
2. DBA (List additional DBA's on separate sheet if necessary.)			10. Facility Telephone Number ( )	11. Facility FAX Number ( )	
3. Facility Address (number, street)			12. 24-Hour Emergency Telephone Number ( )	13. E-mail Address	
4. Facility Address (continued)			14. Correspondent (name and title)		
5. City	State	ZIP Code	15. Correspondent Telephone Number ( )	16. Correspondent FAX Number ( )	
6. Mailing Address (if different or P.O. Box number)			17. Country (if other than United States)	18. FDA CFN or FEI Number	
7. Mailing Address (continued)			19. Website (URL)		
8. City	State	ZIP Code	20. Interstate Commerce ☐ Product Shipped ☐ Product or Raw Materials Received ☐ N/A		

21. Type of Ownership
☐ Individual/Sole Proprietorship ☐ Partnership ☐ Corporation/Limited Liability Company ☐ Nonprofit ☐ Other:_____

22. Corporate Name (if applicable)	State of Incorporation
23. Owners' or Officers' Names and Titles	Owners' or Officers' Names and Titles

24. Stage of Manufacture at Date of Application (check all that apply)
☐ Manufacturing Products ☐ Design Development ☐ Design Validation ☐ Pre-production Design Transfer ☐ Other: _____

25. Intended Device Destination (check all that apply)
☐ Investigational Studies ☐ Export Market ☐ California Distribution ☐ U.S. Distribution ☐ Other: _____

26. Check Each Product Area that Applies to the Devices Manufactured

☐ 862 Clinical Chemistry and Clinical Toxicology	☐ 874 Ear, Nose, and Throat	☐ 886 Ophthalmic
☐ 864 Hematology and Pathology	☐ 876 Gastroenterology/Urology	☐ 888 Orthopedic
☐ 866 Immunology and Microbiology	☐ 878 General and Plastic Surgery	☐ 890 Physical Medicine
☐ 868 Anesthesiology	☐ 880 General Hospital and Personal Use	☐ 892 Radiology
☐ 870 Cardiovascular	☐ 882 Neurological	☐ Unclassified Devices
☐ 872 Dental	☐ 884 Obstetrical and Gynecological	

27. List the types of classified and/or unclassified manufactured devices in the spaces below. Use additional sheets if necessary.

Federal Classification Title	Classification (Check One) I	II	III

28. Identify the manufacturing processes employed or planned in the manufacture of the devices listed above, and if activities will be done in-house or by contract. Use additional sheets if necessary.

Process/Activities	In-House	Contract	Process/Activities	In-House	Contract
Sterilization			Repackaging/Relabeling		
Software Development			Remanufacturing/Refurbishing		
Circuit Board Assembly			Tissue/Cell Culture		
Lyophilization			Other:		
Antigen/Antibodies					

LICENSE FEE: $447.18

MAKE CHECKS PAYABLE TO: DEPARTMENT OF HEALTH SERVICES
See page 2 for mailing address.

The Food and Drug Branch MUST BE NOTIFIED of any change in the application information as provided by California Health and Safety Code §111630.

By signature, I declare under penalty of perjury that all information provided herein is true and correct.

29. Signature of Applicant	Printed name	Title	Date

PLEASE DO NOT WRITE BELOW THIS LINE.

License Number	Expiration Date	Date Received	Payment Type	Amount
				$

Medical Device Manufacturing License Application Instructions

A separate application is required for each place of business. Please complete and/or amend this application as is most appropriate to your facility. Include the appropriate fee for each application as indicated in the fee schedule and payable to: DEPARTMENT OF HEALTH SERVICES. This fee must accompany this application or the application cannot be processed. For renewals, penalty for failure to apply within 30 days after expiration is an additional $10 that must be added to the renewal fee before the license is issued. Unsigned or incomplete applications cannot be processed. The following are further instructions on how to complete this application:

New Applicant / Renewal Applicant: Place an (X) in the box next to New Applicant if your firm has not previously applied for a Device Manufacturing License at this location while under the current ownership. Place an (X) in the box next to Renewal Applicant if your firm has already obtained a Device Manufacturing License for this location, and you are renewing that license. If your firm has changed location, ownership, or both, place an (X) in the box adjacent to the appropriate response.

1. **Name of Firm:** Enter full name of business, corporation, company, or organization applying for licensure.
2. **DBA:** Enter any other name(s) your company is doing business as.

3.–5. **Facility Address:** Enter the street, city, state, and ZIP code for this facility location.

6.–8. **Mailing Address:** Enter full mailing address if different from the facility address.

9. **Facility Operator:** Enter the full name of the person who is responsible for the manufacturing of medical devices at this facility and their title.
10. **Facility Telephone Number:** Enter daytime business telephone number of this facility.
11. **Facility FAX Number:** Enter facility FAX number.
12. **24 Hour Emergency Telephone Number:** Enter telephone number to be called in the event of an emergency.
13. **E-mail Address:** Enter facility email address.
14. **Correspondent:** Enter the name of the person to contact for information regarding this application and their title.
15. **Correspondent Telephone Number:** Enter the daytime business telephone number of the contact person.
16. **Correspondent FAX Number:** Enter the daytime business FAX number of the contact person.
17. **Country:** Enter the country where your facility is located if outside of the United States.
18. **FDA CFN or FEI:** Enter your U.S. Food and Drug Administration Central File Number or Federal Establishment ID if known.
19. **Website:** Enter the website address for your business if applicable.
20. **Interstate Commerce:** Place an (X) in the boxes that correctly describe your business' receipt or distribution of products or materials through or into interstate commerce.
21. **Type of Ownership:** Place an (X) in the box next to the appropriate legal description of the facility's ownership.
22. **Corporate Name:** Enter corporate name if applicable. Enter the state of incorporation if applicable.
23. **Owner's or Officer's Names:** List the business owners' or officers' names and titles.
24. **Stage of Manufacture:** Place an (X) in the box next to the stage of manufacture your products are in at the time of application submission. Check all that apply.
25. **Intended Device Destination:** Place an (X) in the box adjacent to the destination(s) for your manufactured products. Check all that apply.
26. **Products Manufactured:** Place an (X) in the box adjacent to each product area box that applies to the devices manufactured or to be manufactured.
27. **Classified or Unclassified Devices Manufactured:** For each medical device product, list the federal classification name and classification category (I, II, or III) as listed in 21 CFR, Sections 862 to 892.
    [See http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfrv8_00.html and http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.]
    If not known or if thought to be unclassified, please provide your best description for each device. Use additional sheets if necessary.
28. **Manufacturing Processes:** Place an (X) in the column adjacent to any indicated processes to identify if they will be done in-house or contracted-out. Leave line blank if the indicated process will not be used in the manufacture of listed devices. List additional processes or methods as needed herein or on additional sheets if necessary.
29. **Sign the application, print your name, print your title, and enter the date.**

MAKE CHECKS PAYABLE TO: **DEPARTMENT OF HEALTH SERVICES**

MAIL APPLICATION AND CHECK TO:
California Department of Health Services
Accounting Section/Cashiers
MS 1101
1501 Capitol Avenue
P.O. Box 997415
Sacramento, CA 95899-7415

If you have any further questions, please contact the Food and Drug Branch, Device and Drug License Desk at (916) 650-6500 or visit our website at: http://www.dhs.ca.gov/fdb/ .